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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,265

08/19/2003

Jeffry G. Weers

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/644,265

Applicant(s)

WEERS ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-29, 133-138, 140-144, and 146-207 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-29, 133-138, 140-144, 146-169, 171-180, 183-186, 188-190 and 193-207 is/are rejected.
- 7) ☒ Claim(s) 170, 181-182, 187, and 191-192 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1-7, 9-29, 133-138, 140-144, and 146-207 are pending. Applicants cancelled claim 145 in the currently amended claim set. Applicants amended claims 13, 26-27, 133-134, 144, 147, 149, 160-161, 170-171, 183-184, 192-193, 196, and 202. Receipt and consideration of Applicants' amended claim set, terminal disclaimers, and remarks/arguments submitted on November 9, 2006 is acknowledged.

Priority

Claims 27, 149, 171, 193, and 202 are not granted benefit of priority to parent applications 09/133,848 and 09/106,932, because these claims lack support for a Markush group of bioactive agents that includes vaccines in the cited parent applications. Claims 27, 149, 171, 193, and 202 are not granted benefit of provisional 60/060,337, because these claims lack support for a Markush group of bioactive agents that includes vaccines.

Moot Rejections/objections

All rejections and/or objections of claim 145 cited in the previous office action mailed on May 9, 2006 **are moot**, because said claim has been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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The rejection of claims 1-7 and 9-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants' persuasive arguments.

The rejection of claims 170 and 192 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicants' amendments removing the indefinite terminology (i.e. deleting "substantially").

Response to Arguments

Applicant's arguments, see pages 21-22, filed November 9, 2006, with respect to claims 1-7 and 9-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been fully considered and are persuasive. The rejection of claims 1-7, 9-29, 170, and 192 has been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). The terminal disclaimers submitted on November 9, 2006 for U.S. Patent Nos. 6,630,169; 6,309,623; and 6,638,495 have not been approved. The Examiner has reviewed all the documents in the prosecution history of the instant application and did not find any document granting power of Attorney to Mr. Ashok K. Janah, Esq. Therefore, Mr. Janah is not an attorney of record.

The rejection of claims 1-7, 9-29, 133-138, 140-150, and 151-159, 161, 166-169, and 171-173 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 9-29 and 72-87 of U.S. Patent No. 6,309,623 **is maintained** based upon the reasoning discussed on pages 14-17 of the office action mailed on October 7, 2005.

The rejection of claims 1, 133-134, 136, 138, 143, 144, and 147-150 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5-6, 8-11, 13, 14, and 16 of U.S. Patent No. 6,630,169 **is maintained** based upon the reasoning discussed on pages 17-20 of the office action mailed on October 7, 2005.

The rejection of claims 151-159, 161, 166-169, and 171-173 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 5-6, 8-11, 13, 14, and 16 of U.S. Patent No. 6,630,169 **is maintained** based upon the reasoning discussed on pages 14-17 of the office action mailed on October 7, 2005.

The rejection of claims 1-7, 9-29, 133-138, 140-164, 166-196, 199-202, and 205-207 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-20 of U.S. Patent No. 6,638,495 (USPN '495) Platz et al. (WO 91/16038) **is maintained** for the reasons of record set forth on pages 5-7 of the office action mailed on May 9, 2006.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 1, 6, 10, 12-15, 133, 134, 138, and 148 as being unpatentable over claims 1-5 and 12 of copending Application No. 11/317,523 (copending '523) **is maintained** for the reasons of record set forth on pages 7 of the previous office action mailed on May 9, 2006.

The provisional rejection on the ground of nonstatutory obviousness-type double patenting of claims 1, 6, 10, 12-15, 21-23, 27-29, 133, 134, 138, 141, 143-144, 147-151, 156, 157, 159, 161, 165-168, 171-174, 180, 184, 188-190, 193-207 as being unpatentable over claims 1, 5-7, 9, 12-15, and 18 of copending Application No. 11/317,839 (copending '839) **is maintained** for the reasons of record set forth on pages 7-8 of the previous office action mailed on May 9, 2006.

Response to Arguments

Applicant's arguments filed November 9, 2006 have been fully considered but they are not persuasive. Applicants' have not posited any substantive arguments traversing the above cited outstanding non-provisional and provisional obviousness-type double patenting rejections. The terminal disclaimers submitted on November 9, 2006 over U.S. Patent Nos. 6,630,169; 6,309,623; and 6,638,495 have not been approved and therefore these rejections remain proper.

Claims 2-7, 9, 11-13, 15, 17-19, 26-28, 151-155, 162-163, 171, 174-178, 183, 185-186, 193, and 196-197 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 10-14, 16-17, 21, 25, 27-29, 30, 32, and 34-35 of copending application 09/999,071 ("allowed application '071"), which has been allowed, but has not yet been assigned a U.S. Patent No.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. For example, dependent claim 2 of allowed application '071 claims a method of making a stabilized dispersion comprising providing a fluorochemical suspension medium, and dispersing therein a plurality of perforated microstructures in the suspension medium, wherein the perforated microstructures comprises a surfactant and is substantially permeated by the suspension medium. Dependent claim 2 of the instant application claims a respiratory dispersion comprising a suspension medium having dispersed therein a plurality of perforated microstructures comprising at least one bioactive agent and wherein the suspension medium comprises at least one propellant comprising a compound selected from the group consisting of 1,1,1,2-tetrafluoroethane,

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1,1,1,2,3,3,3-heptafluoro-n-propane, perfluoroethane, monochlorodifluoromethane, 1,1-difluoroethane and combinations thereof (i.e. the propellant is a fluorochemical). The method claims of allowed application '071 therefore, result in the respiratory particles of the cited claims of the instant application. Therefore, an ordinary skilled artisan would have found claims 2-7, 9, 11-13, 15, 17-19, 26-28, 151-155, 162-163, 171, 174-178, 183, 185-186, 193, and 196-197 *prima facie* obvious over the cited claims of allowed application '071.

Allowable Subject Matter

Claims 170, 181-182, 187, 191-192 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-7, 9-29, 133-138, 140-144, 146-169, 171-180, 183-186, 188-190, and 193-207 are rejected. Claims 170, 181-182, 187, and 191-192 are objected. No claims are allowed.

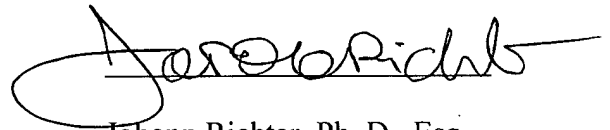
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
Technology Center 1600

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph. D., Esq.
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Technology Center 1600